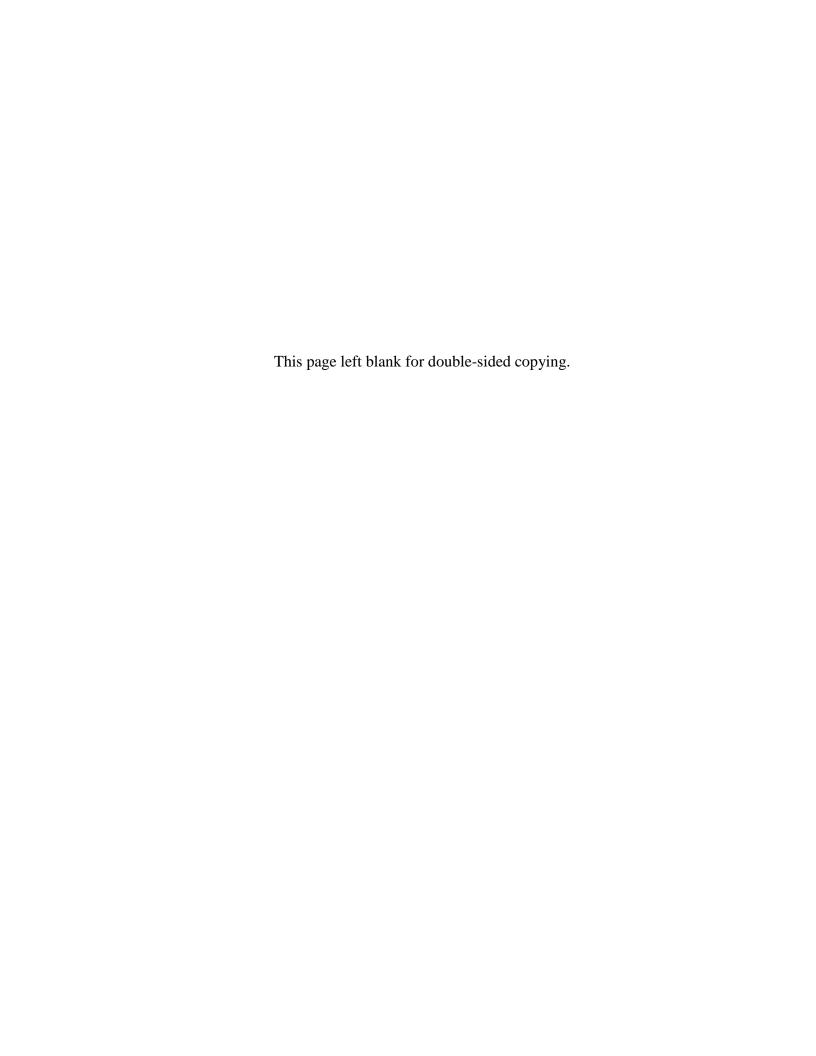
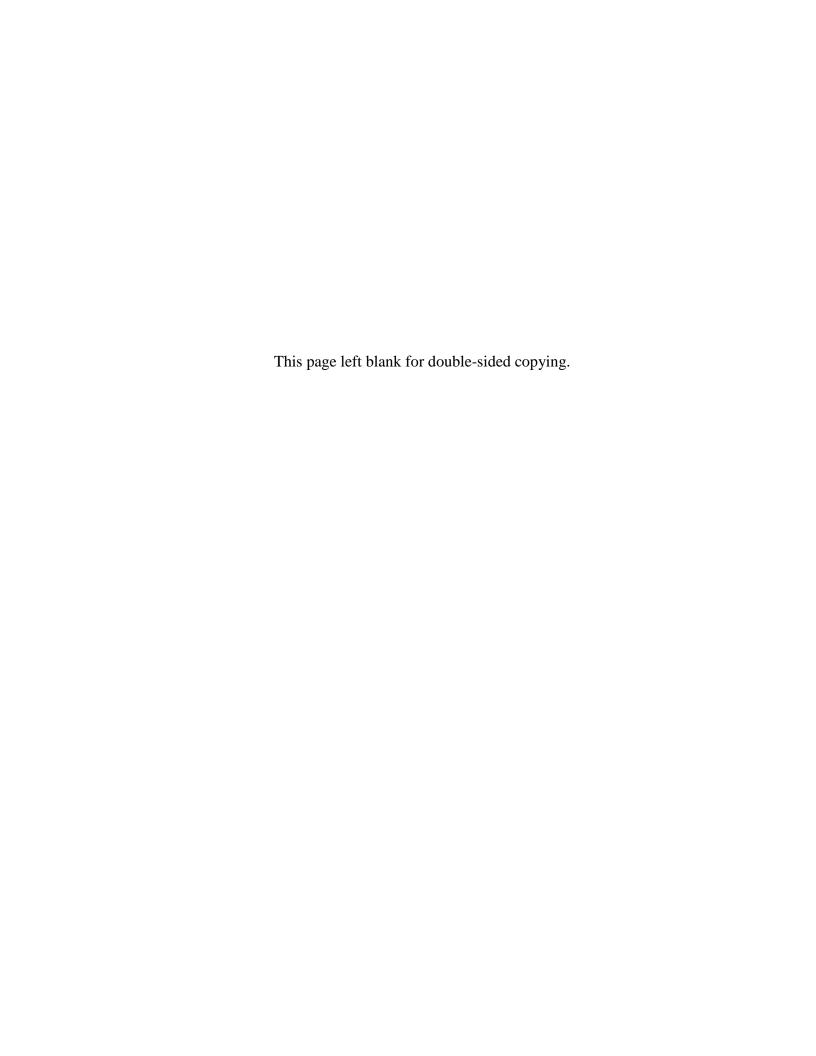
# ATTACHMENT A AUTHORIZING LEGISLATION



<b>A.1</b> .	Breast and Cervical Cancer Mortality Prevention Act of 1990						





# Breast and Cervical Cancer Mortality Prevention Act of 1990

The Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354) established the Centers for Disease Control and Prevention's National Breast and Cervical Cancer Early Detection Program. The program provides breast and cervical cancer screening exams to underserved women, including those who are older, have low incomes, or are members of racial and ethnic minority groups. The program operates in all 50 states, the District of Columbia, five U.S. territories, and 11 American Indian/ Alaska Native organizations.

This document contains the text of the legislation that established the program (Title 42 USC § 300k), its amendments, and directly related legislation.

# Title 42. The Public Health and Welfare Chapter 6a. The Public Health Service Preventive Health Measures with Respect to Breast and Cervical Cancers

42 U.S.C. § 300k

Note: Amendments to 42 USC § 300k are indicated in bold and italics, followed by a reference to the amending law in parentheses. Links to related legislation are provided in the text.

#### § 300k. Establishment of program of grants to States

- (a) In general. The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States on the basis of an established competitive review process for the purpose of carrying out programs—
  - (1) to screen women for breast and cervical cancer as a preventive health measure;
  - (2) to provide appropriate referrals for medical treatment of women screened pursuant to paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services and support services such as case management (Women's Health Research and Prevention Amendments of 1998, Public Law 105-340);
  - (3) to develop and disseminate public information and education programs for the detection and control of breast and cervical cancer;
  - (4) to improve the education, training, and skills of health professionals (including allied health professionals) in the detection and control of breast and cervical cancer;
  - (5) to establish mechanisms through which the States can monitor the quality of screening procedures for breast and cervical cancer, including the interpretation of such procedures; and

- (6) to evaluate activities conducted under paragraphs (1) through (5) through appropriate surveillance or program-monitoring activities.
- (b) Grant and contract authority of States.
  - (1) In general. A state receiving a grant under subsection (a) may, subject to paragraphs (2) and (3), expend the grant to carry out the purpose described in such subsection through grants to public and non profit private entities and through contracts with public and private entities (Women's Health Research and Prevention Amendments of 1998, Public Law 105-340).
  - (2) CERTAIN APPLICATIONS- If a nonprofit private entity and a private entity that is not a nonprofit entity both submit applications to a State to receive an award of a grant or contract pursuant to paragraph (1), the State may give priority to the application submitted by the nonprofit private entity in any case in which the State determines that the quality of such application is equivalent to the quality of the application submitted by the other private entity (Women's Health Research and Prevention Amendments of 1998, Public Law 105-340).
  - (3) Payments for screenings. The amount paid by a State to an entity under this subsection for a screening procedure under subsection (a)(1) may not exceed the amount that would be paid under part B of title XVIII of the Social Security Act [42 U.S.C. §§ 1395j et seq.] if payment were made under such part for furnishing the procedure to a woman enrolled under such part.

#### (Legislation Related to this Provision (#Public Law 106-113))

- (c) Special consideration for certain States. In making grants under subsection (a) to States whose initial grants under such subsection are made for fiscal year 1995 or any subsequent fiscal year, the Secretary shall give special consideration to any State whose proposal for carrying out programs under such subsection—
  - (1) has been approved through a process of peer review; and
  - (2) is made with respect to geographic areas in which there is—
    - (A) a substantial rate of mortality from breast or cervical cancer; or
    - (B) a substantial incidence of either of such cancers.
- [(d)](c) Coordinating committee regarding year 2000 health objectives. The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a committee to coordinate the activities of the agencies of the Public Health Service (and other appropriate Federal agencies) that are carried out toward achieving the objectives established by the Secretary for reductions in the rate of mortality from breast and cervical cancer in the United States by the year 2000. Such committee shall be comprised of Federal officers or employees designated by the heads of the agencies involved to serve on the committee as representatives of the agencies, and such representatives from other public or private entities as the Secretary determines to be appropriate.

## § 300l. Requirement of matching funds

- (a) In general. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees, with respect to the costs to be incurred by the State in carrying out the purpose described in such section, to make available non-Federal contributions (in cash or in kind under subsection (b)) toward such costs in an amount equal to not less than \$1 for each \$3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.
- (b) Determination of amount of non-Federal contribution.
  - (1) In general. Non-Federal contributions required in subsection (a) may be in cash or in kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.
  - (2) Maintenance of effort. In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the State involved toward the purpose described in section 1501 [42 U.S.C. § 300k] for the 2-year period preceding the first fiscal year for which the State is applying to receive a grant under such section.
  - (3) Inclusion of relevant non-Federal contributions for Medicaid. In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary shall, subject to paragraphs (1) and (2) of this subsection, include any non-Federal amounts expended pursuant to title XIX of the Social Security Act [42 U.S.C. § 1396 et seq.] by the State involved toward the purpose described in paragraphs (1) and (2) of section 1501(a) [42 U.S.C. § 300k(a)].

## § 300l-1. Requirement regarding medicaid

The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] for a program in a State unless the State plan under title XIX of the Social Security Act [42 U.S.C. §§ 1396 et seq.] for the State includes the screening procedures specified in subparagraphs (A) and (B) of section 1503(a)(2) [42 U.S.C. § 300m(a)(2)(A), (B)] as medical assistance provided under the plan.

## § 300m. Requirements with respect to type and quality of services

- (a) Requirement of provision of all services by date certain. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees—
  - (1) to ensure that, initially and throughout the period during which amounts are received pursuant to the grant, not less than 60 percent of the grant is expended to provide each of the services or activities described in paragraphs (1) and (2) of section 1501(a) [42 U.S.C. § 300k(a)], including making available screening procedures for both breast and cervical cancers;
  - (2) subject to subsection (b), to ensure that—
    - (A) in the case of breast cancer, both a physical examination of the breasts and the screening procedure known as a mammography are conducted; and

- (B) in the case of cervical cancer, both a pelvic examination and the screening procedure known as a pap smear are conducted;
- (3) to ensure that, by the end of any second fiscal year of payments pursuant to the grant, each of the services or activities described in section 1501(a) [42 U.S.C. § 300k (a)] is provided; and
- (4) to ensure that not more than 40 percent of the grant is expended to provide the services or activities described in paragraphs (3) through (6) of such section.
- (b) Use of improved screening procedures. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that, if any screening procedure superior to a procedure described in subsection (a)(2) becomes commonly available and is recommended for use, any entity providing screening procedures pursuant to the grant will utilize the superior procedure rather than the procedure described in such subsection.
- (c) Quality assurance regarding screening procedures. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that the State will, in accordance with applicable law, assure the quality of screening procedures conducted pursuant to such section.

#### (d) Waiver of Services Requirement on Division of Funds -

- (1) IN GENERAL- The Secretary shall establish a demonstration project under which the Secretary may waive the requirements of paragraphs (1) and (4) of subsection (a) for not more than 5 States, if—
  - (A) the State involved will use the waiver to leverage non-Federal funds to supplement each of the services or activities described in paragraphs (1) and (2) of section 1501(a);
  - (B) the application of such requirement would result in a barrier to the enrollment of qualifying women;
  - (C) the State involved—
    - (i) demonstrates, to the satisfaction of the Secretary, the manner in which the State will use such waiver to expand the level of screening and follow-up services provided immediately prior to the date on which the waiver is granted; and
    - (ii) provides assurances, satisfactory to the Secretary, that the State will, on an annual basis, demonstrate, through such documentation as the Secretary may require, that the State has used such waiver as described in clause (i);
  - (D) the State involved submits to the Secretary-
    - (i) assurances, satisfactory to the Secretary, that the State will maintain the average annual level of State fiscal year expenditures for the services and activities described in paragraphs (1) and (2) of section 1501(a) for the period for which

the waiver is granted, and for the period for which any extension of such wavier is granted, at a level that is not less than—

- (I) the level of the State fiscal year expenditures for such services and activities for the fiscal year preceding the first fiscal year for which the waiver is granted; or
- (II) at the option of the State and upon approval by the Secretary, the average level of the State expenditures for such services and activities for the 3-fiscal year period preceding the first fiscal year for which the waiver is granted; and
- (ii) a plan, satisfactory to the Secretary, for maintaining the level of activities carried out under the waiver after the expiration of the waiver and any extension of such waiver;
- (E) the Secretary finds that granting such a waiver to a State will increase the number of women in the State that receive each of the services or activities described in paragraphs (1) and (2) of section 1501(a), including making available screening procedures for both breast and cervical cancers; and
- (F) the Secretary finds that granting such a waiver to a State will not adversely affect the quality of each of the services or activities described in paragraphs (1) and (2) of section 1501(a).

#### (2) DURATION OF WAIVER-

- (A) IN GENERAL- In granting waivers under paragraph (1), the Secretary—
  - (i) shall grant such waivers for a period that is not less than 1 year but not more than 2 years; and
  - (ii) upon request of a State, may extend a waiver for an additional period that is not less than 1 year but not more than 2 years in accordance with subparagraph (B).
- (B) ADDITIONAL PERIOD- The Secretary, upon the request of a State that has received a waiver under paragraph (1), shall, at the end of the waiver period described in subparagraph (A)(i), review performance under the waiver and may extend the waiver for an additional period if the Secretary determines that—
  - (i) without an extension of the waiver, there will be a barrier to the enrollment of qualifying women;
  - (ii) the State requesting such extended waiver will use the waiver to leverage non-Federal funds to supplement the services or activities described in paragraphs (1) and (2) of section 1501(a);
  - (iii) the waiver has increased, and will continue to increase, the number of women in the State that receive the services or activities described in paragraphs (1) and (2) of section 1501(a);

- (iv) the waiver has not, and will not, result in lower quality in the State of the services or activities described in paragraphs (1) and (2) of section 1501(a); and
- (v) the State has maintained the average annual level of State fiscal expenditures for the services and activities described in paragraphs (1) and (2) of section 1501(a) for the period for which the waiver was granted at a level that is not less than—
  - (I) the level of the State fiscal year expenditures for such services and activities for the fiscal year preceding the first fiscal year for which the waiver is granted; or
  - (II) at the option of the State and upon approval by the Secretary, the average level of the State expenditures for such services and activities for the 3-fiscal year period preceding the first fiscal year for which the waiver is granted.
- 3) REPORTING REQUIREMENTS- The Secretary shall include as part of the evaluations and reports required under section 1508, the following:
  - (A) A description of the total amount of dollars leveraged annually from Non-Federal entities in States receiving a waiver under paragraph (1) and how these amounts were used.
  - (B) With respect to States receiving a waiver under paragraph (1), a description of the percentage of the grant that is expended on providing each of the services or activities described in—
    - (i) paragraphs (1) and (2) of section 1501(a); and
    - (ii) paragraphs (3) through (6) of section 1501(a).
  - (C) A description of the number of States receiving waivers under paragraph (1) annually.
  - (D) With respect to States receiving a waiver under paragraph (1), a description of—
    - (i) the number of women receiving services under paragraphs (1), (2), and (3) of section 1501(a) in programs before and after the granting of such waiver; and
    - (ii) the average annual level of State fiscal expenditures for the services and activities described in paragraphs (1) and (2) of section 1501(a) for the year preceding the first year for which the waiver was granted.
- (4) LIMITATION- Amounts to which a waiver applies under this subsection shall not be used to increase the number of salaried employees.
- (5) DEFINITIONS- In this subsection:

- (A) INDIAN TRIBE- The term "Indian tribe" has the meaning given the term in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).
- (B) TRIBAL ORGANIZATION- The term "tribal organization" has the meaning given the term in section 4 of the Indian Health Care Improvement Act.
- (C) STATE- The term "State" means each of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of the Marshall Islands, the Federated States of Micronesia, the Republic of Palau, an Indian tribe, and a tribal organization.
- (6) SUNSET- The Secretary may not grant a waiver or extension under this subsection after September 30, 2012.

#### § 300n. Additional required agreements

- (a) Priority for low-income women. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that low-income women will be given priority in the provision of services and activities pursuant to paragraphs (1) and (2) of section 1501(a) [42 U.S.C. § 300k(a)].
- (b) Limitation on imposition of fees for services. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—
  - (1) will be made according to a schedule of charges that is made available to the public;
  - (2) will be adjusted to reflect the income of the woman involved; and
  - (3) will not be imposed on any woman with an income of less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981 [42 U.S.C. § 9902(2)].
- (c) Statewide provision of services.
  - (1) In general. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that services and activities under the grant will be made available throughout the State, including availability to members of any Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act [25 U.S.C. § 450b]).
  - (2) Waiver. The Secretary may waive the requirement established in paragraph (1) for a State if the Secretary determines that compliance by the State with the requirement would result in an inefficient allocation of resources with respect to carrying out the purpose described in section 1501(a) [42 U.S.C. § 300k(a)].
  - (3) Grants to tribes and tribal organizations.

- (A) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to tribes and tribal organizations (as such terms are used in paragraph (1)) for the purpose of carrying out programs described in section 1501(a) [42 U.S.C. § 300k(a)]. This title applies to such a grant (in relation to the jurisdiction of the tribe or organization) to the same extent and in the same manner as such title applies to a grant to a State under section 1501 [42 U.S.C. § 300k] (in relation to the jurisdiction of the State).
- (B) If a tribe or tribal organization is receiving a grant under subparagraph (A) and the State in which the tribe or organization is located is receiving a grant under section 1501 [42 U.S.C. § 300k], the requirement established in paragraph (1) for the State regarding the tribe or organization is deemed to have been waived under paragraph (2).
- (d) Relationship to items and services under other programs. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that the grant will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—
  - (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or
  - (2) by an entity that provides health services on a prepaid basis.
- (e) Coordination with other breast and cervical cancer programs. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that the services and activities funded through the grant shall be coordinated with other Federal, State, and local breast and cervical cancer programs.
- (f) Limitation on administrative expenses. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.
- (g) Restrictions on use of grant. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that the grant will not be expended to provide inpatient hospital services for any individual.
- (h) Records and audits. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees that—
  - (1) the State will establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the State under such section; and
  - (2) upon request, the State will provide records maintained pursuant to paragraph (1) to the Secretary or the Comptroller of the United States for purposes of auditing the expenditures by the State of the grant.
- (i) Reports to Secretary. The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless the State involved agrees to submit to the Secretary such reports as the Secretary may require with respect to the grant.

## § 300n-1. Description of intended uses of grant

The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless—

- (1) the State involved submits to the Secretary a description of the purposes for which the State intends to expend the grant;
- (2) the description identifies the populations, areas, and localities in the State with a need for the services or activities described in section 1501(a) [42 U.S.C. § 300k(a)];
- (3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public and nonprofit private entities; and
- (4) the description provides assurances that the grant funds will be used in the most costeffective manner.

## § 300n-2. Requirement of submission of application

The Secretary may not make a grant under section 1501 [42 U.S.C. § 300k] unless an application for the grant is submitted to the Secretary, the application contains the description of intended uses required in section 1505 [42 U.S.C. § 300n-1], and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this title [42 U.S.C. §§ 300k et seq.].

# § 300n-3. Technical assistance and provision of supplies and services in lieu of grant funds

- (a) Technical assistance. The Secretary may provide training and technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to section 1501 [42 U.S.C. § 300k]. The Secretary may provide such technical assistance directly or through grants to, or contracts with, public and private entities.
- (b) Provision of supplies and services in lieu of grant funds.
  - (1) In general. Upon the request of a State receiving a grant under section 1501 [42 U.S.C. § 300k], the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out such section and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.
  - (2) Corresponding reduction in payments. With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under the grant under section 1501 [42 U.S.C. § 300k] to the State involved by an amount equal to the costs of detailing personnel (including pay, allowances, and travel expenses) and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

#### § 300n-4. Evaluations and reports

(a) Evaluations. The Secretary shall, directly or through contracts with public private entities, provide for annual evaluations of programs carried out pursuant to section 1501

- [42 U.S.C. § 300k]. Such evaluations shall include evaluations of the extent to which States carrying out such programs are in compliance with section 1501(a)(2) [42 U.S.C. § 300k(a) (2)] and with section 1504© [42 U.S.C. § 300n(c)].
- (b) Report to Congress. The Secretary shall, not later than 1 year after the date on which amounts are first appropriated pursuant to section 1509(a) [42 U.S.C. § 300n-5(a)], and annually thereafter, submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report summarizing evaluations carried out pursuant to subsection (a) during the preceding fiscal year and making such recommendations for administrative and legislative initiatives with respect to this title [42 U.S.C. §§ 300k et seq.] as the Secretary determines to be appropriate, including recommendations regarding compliance by the States with section 1501(a)(2) [42 U.S.C. § 300k(a)(2)] and with section 1504© [42 U.S.C. § 300n(c)].

## § 300n-4a. Supplemental grants for additional preventive health services

- (a) Demonstration projects. In the case of States receiving grants under section 1501 [42 U.S.C. § 300k], the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to not more than 3 such States to carry out demonstration projects for the purpose of—
  - (1) providing preventive health services in addition to the services authorized in such section, including screenings regarding blood pressure and cholesterol, and including health education;
  - (2) providing appropriate referrals for medical treatment of women receiving services pursuant to paragraph (1) and ensuring, to the extent practicable, the provision of appropriate follow-up services; and
  - (3) evaluating activities conducted under paragraphs (1) and (2) through appropriate surveillance or program-monitoring activities.
- (b) Status as participant in program regarding breast and cervical cancer. The Secretary may not make a grant under subsection (a) unless the State involved agrees that services under the grant will be provided only through entities that are screening women for breast or cervical cancer pursuant to a grant under section 1501 [42 U.S.C. § 300k].
- (c) Applicability of provisions of general program. This title [42 U.S.C. §§ 300k et seq.] applies to a grant under subsection (a) to the same extent and in the same manner as such title applies to a grant under section 1501[42 U.S.C. § 300k].

#### (d) Funding.

- (1) In general. Subject to paragraph (2), for the purpose of carrying out this section, there are authorized to be appropriated \$3,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 **through 2003** (Women's Health Research and Prevention Amendments of 1998, Public Law 105-340).
- (2) Limitation regarding funding with respect to breast and cervical cancer. The authorization of appropriations established in paragraph (1) is not effective for a fiscal

year unless the amount appropriated under section 1510(a) [42 U.S.C. § 300n-5(a)] for the fiscal year is equal to or greater than \$ 100,000,000.

#### § 300n-5. Funding for general program

- (a) Authorization of appropriations. For the purpose of carrying out this title [42 U.S.C. §§ 300k et seq.], there are authorized to be appropriated \$50,000,000 for fiscal year 1991, such sums as may be necessary for each of the fiscal years 1992 and 1993, \$150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003 (Women's Health Research and Prevention Amendments of 1998, Public Law 105-340).
- (b) Set-aside for technical assistance and provision of supplies and services. Of the amounts appropriated under subsection (a) for a fiscal year, the Secretary shall reserve not more than 20 percent for carrying out section 1507 [42 U.S.C. § 300n-3].

#### Legislation Related to 42 U.S.C. § 300k

Public Law 106-113 (The Balanced Budget Refinement Act of 1999), Section 224. Increase in reimbursement for pap smears. Passed 11/29/99. Related to 42 U.S.C. § 300k(b) (3).

- (a) Pap Smear Payment Increase.—Section 1833(h) (42 U.S.C. 1395l(h)) is amended by adding at the end the following new paragraph: "(7) Notwithstanding paragraphs (1) and (4), the Secretary shall establish a national minimum payment amount under this subsection for a diagnostic or screening pap smear laboratory test (including all cervical cancer screening technologies that have been approved by the Food and Drug Administration as a primary screening method for detection of cervical cancer) equal to \$14.60 for tests furnished in 2000. For such tests furnished in subsequent years, such national minimum payment amount shall be adjusted annually as provided in paragraph (2)."
- (b) Sense of Congress.—It is the sense of the Congress that—
  - (1) the Health Care Financing Administration has been slow to incorporate or provide incentives for providers to use new screening diagnostic health care technologies in the area of cervical cancer:
  - (2) some new technologies have been developed which optimize the effectiveness of pap smear screening; and
  - (3) the Health Care Financing Administration should institute an appropriate increase in the payment rate for new cervical cancer screening technologies that have been approved by the Food and Drug Administration and that are significantly more effective than a conventional pap smear.

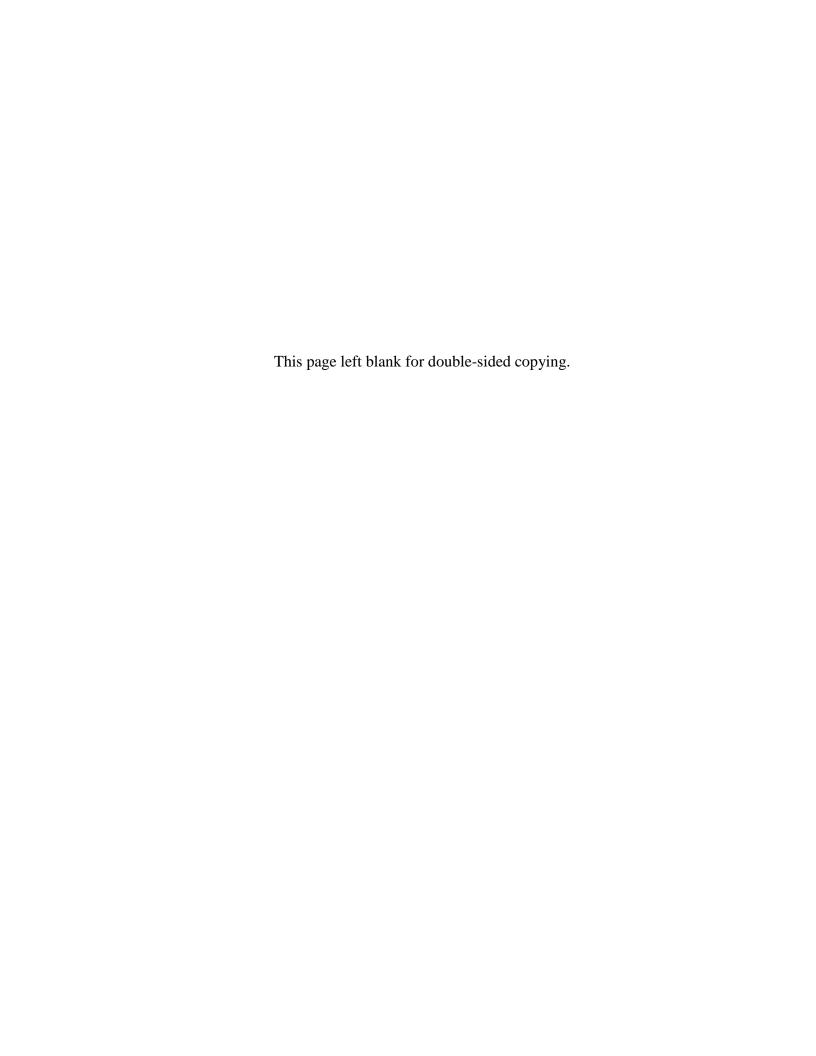
#### (Return to Title 42 USC § 300k[b][3] (#300-b-3))

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A.2.	Section	301	of the	<b>Public</b>	Health	<b>Service A</b>	ct
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## TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

#### PART A—RESEARCH AND INVESTIGATION

#### IN GENERAL

SEC. 301. [241] (a) The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to—

(1) collect and make available through publications and other appropriate means, information as to, and the practical

application of, such research and other activities;

(2) make available research facilities of the Service to appropriate public authorities, and to health officials and sci-

entists engaged in special study;

(3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars,

and consultants from the United States or abroad;

(5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise el-

igible for such treatment;

- (6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;
- (7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under title 10, United States Code, sections 2353 and 2354, except that determination, approval, and certification required thereby shall be by the Secretary of Health, Education, and Welfare; and

(8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as

the Secretary determines appropriate.

- (b)(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

  (2)(A) The Secretary shall establish a comprehensive program
- (2)(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts
- (B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.
- (3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health, Education, and Welfare and shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.
- (4) The Secretary shall publish a biennial report which contains—
  - (A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;
  - (B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;
  - (C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient,

or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

(D) a description of (i) each request received during the

year involved-

(I) from a Federal agency outside the Department of Health, Education, and Welfare for the Secretary, or

(II) from an entity within the Department of Health, Education, and Welfare to any other entity within the Department.

to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in Appropriation Acts.

(c) The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

(e) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand, intensify, and coordinate the activities of the Centers for Disease Control and Prevention with respect to preterm labor and delivery and infant mor-

tality.